

K060500

27-5 Leui-Dong, Yeongtong-Gu, Suwon-Si, Gyeonggi-Do, Korea 442-270
Tel 82 31 207-2200 Fax 82 31 207-3933

Dentium

510(k) Summary

JUN 16 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 21, 2006

1. Company and Correspondent making the submission:

	Company
Name	Dentium Co., Ltd.
Address	27-5 Leui-Dong, Yeongtong-Gu, Suwon-Si, Gyeonggi-Do, Korea 442-270
Phone	+82 31 207-2200
Fax	+82 31 207-3933
Contact	K. Y. Yoon

2. Device:

Proprietary Name – Speedy Orthodontic Screw

Common Name – Small bone screw

Classification Name – Endosseous dental implant

3. Predicate Device:

Dual Top Anchor System Screws, Jeil Medical Corporation, K033767

4. Classifications Names & Citations:

21CFR 872.3640, DZE, Endosseous dental implant, Class2

5. Description:

Speedy Orthodontic Screw is intended to provide a fixed anchorage for orthodontic movement of teeth. It is composed of screw and head; screw is implanted in the maxilla and/or mandible, and head is used for the connection of wire. It is from 5.35-10.5mm in total length and is made of Titanium 6Al-4V alloy. It is used temporarily and is removed after orthodontic treatment has been completed. It is supplied sterile and intended for single use only.

6. Indication for use:

The Speedy Orthodontic Screw is intended for use as temporary anchor for orthodontic treatment.

7. Contra-indications:

- 1) Osteoporosis

- 2) Advanced diabetes
- 3) Metal allergies

8. Review:

Speedy Orthodontic Screw has the same device characteristics as the predicate device. Material, design and use concept is similar.

Speedy Orthodontic Screw has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply to applicable industry and US regulations.

An extensive review of literature pertaining to the safety and biocompatibility of Speedy Orthodontic Screw has been conducted. Appropriate safeguards have been incorporated in the design of Speedy Orthodontic Screw.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Dentium Co., Ltd. concludes that Speedy Orthodontic Screw is safe and effective and substantially equivalent to predicate devices as described herein.

- 10. Dentium Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END



JUN 16 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dentium Company, Limited
C/O Ms. Cathryn N. Cambria
President
Arkin Consulting Group
5536 Trowbridge Drive
Dunwoody, Georgia 30338

Re: K060500
Trade/Device Name: Speedy Orthodontic Screw
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 12, 2006
Received: June 14, 2006

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number K K060500


Device Name: Speedy Orthodontic Screw

Indication for use: The Speedy Orthodontic Screw is intended for use as temporary anchor for orthodontic treatment.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Susan R. [unclear]
[unclear] Sign-Off
[unclear] of Anesthesiology, General Hospital,
[unclear] Control, Dental Devices
510(k) Number: K060500